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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/266,543	03/11/99	HOLADAY J	05213-0075

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EXAMINER	
HOLLERAN, A	
ART UNIT	**PAPER NUMBER**
1642	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/266,543	Holaday et al
Examiner	**Group Art Unit**
Anne Holleran	1642

☒ Responsive to communication(s) filed on *Jan 3, 2001*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *4-49* is/are pending in the applicat

Of the above, claim(s) *30-49* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *4-29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *12*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Applicant's election of species in Paper No. 15, filed January 3, 2001, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 4-49 are pending.

Claims 30-49, drawn to non-elected inventions, are withdrawn from consideration.

Claims 4-29 are examined on the merits. Species of carrier is liposome, species of claim 9 is adjuvants, species of adjuvant is lipophilic muramyl dipeptide, species of hydrophobic moiety is palmitic acid.

Claim Rejections - 35 USC § 112

3. Claims 6 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5. 15 and 25 are vague and indefinite because the claims are drawn to products which "correspond" to a structure. The term "correspond" does not indicate what the structure is

of the claimed product and thus the metes and bounds of the claimed product cannot be determined. This rejection would be obviated if the "corresponds" was replaced by "consists of".

Claim 6 is vague and indefinite because it is drawn to a composition comprising SEQ ID NO: 1 **and** SEQ ID NO: 2 when it appears that the claim should be drawn to a composition comprising either SEQ ID NO: 1 **or** SEQ ID NO: 2.

Claim 16 is vague and indefinite because it is drawn to a composition comprising SEQ ID NOS: 3-9 when it appears that the claim should be drawn to a composition comprising either SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 **or** SEQ ID NO: 9.

4. Claims 4, 5, 14, 15, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that each of the claimed compositions encompass a genus of products which is not supported in scope by the examples and teachings provided by the disclosure of the specification.

Claims 4, 5, 14, 15, 24 and 25 are drawn to immunogenic compositions comprising immunogenic peptide fragments. Claims 4, 14 and 24 are construed to read on compositions comprising any fragment of fibroblast growth factor or vascular endothelial growth factor and include fragments such as one amino acid or an atom derived from one amino acid. Such

fragments may be made immunogenic by conjugation or by the use of adjuvants. Thus, the term immunogenic does not limit the claimed compositions to those comprising peptides. A peptide fragment is construed to encompass peptides and any fragment or portion of a peptide. Claims 5, 15 and 25 which are drawn to peptides corresponding to domains of growth factors are interpreted to encompass peptides which do not necessarily have structures defined as heparin binding domain or receptor binding domain because it is not clear how the term "corresponds" can be used to define the structure of a peptide.

The specification confines its teachings of immunogenic compositions to immunogenic compositions comprising peptides consisting of either SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9. These peptides are not representative of the structures encompassed by the claims 4, 5, 14, 15, 24 and 25. The specification does not teach immunogenic compositions comprising fragments of any of these sequences. Furthermore, the specification does not teach how to add, substitute or delete amino acids from these sequences to arrive at useful peptides for the claimed immunogenic compositions. Thus, the specification does not provide adequate descriptive support for a claimed genus of immunogenic compositions wherein the immunogenic peptide has a structure other than a peptide consisting of either SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9. Thus, it does not appear that Applicant was in possession of claims to compositions where the peptide fragments were undescribed by the specification or "corresponded" to domains of a fibroblast growth factor or a vascular endothelial growth factor.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 4, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kardami et al (Kardami, E. et al, Growth Factors, 4: 69-80, 1990).

Claim 4 is drawn to an immunogenic composition comprising an immunogenic peptide fragment of fibroblast growth factor and a pharmaceutically acceptable carrier.

Kardami et al teaches a fragment of bFGF (amino acids 1-24) conjugated to keyhole limpet hemocyanin used to generate rabbit immune sera (see page 70, 1st column). Thus, Kardami et al teaches an immunogenic composition which is the same as that claimed.

6. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by EP281822 (European Patent Application, Takeda Chemical Industries, Ltd, Senoo, M. et al; published September 14, 1988).

Claims 4-6 are drawn to immunogenic compositions comprising fragments of FGF and a pharmaceutically acceptable carrier. The fragment may comprise the heparin binding domain of FGF or may comprise either SEQ ID NO: 1 or SEQ ID NO: 2.

EP281822 teaches immunization of mice with an FGF mutein combined with Freund's complete adjuvant which results in the production of monoclonal antibodies (see page 43, lines 29-56 and page 21, lines 16-33 and enclosed sequence alignments). Thus, EP281822 teaches immunogenic compositions that are the same as that claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 4-29 are rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-3, 5-8, 15-21, 28, 29, 32 and 33 of U.S. Patent No. 5,919,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4-19 are broadly drawn to compositions comprising fragments of fibroblast growth factor or vascular endothelial growth factor which reads on compositions comprising the entire fibroblast growth factor or vascular endothelial growth factor. Thus, even claims 5, 6, 15 and 16 which recite specific fragments also read on compositions comprising an

entire fibroblast growth factor or vascular endothelial growth factor. Also, to the extent that claims 4-29 read on compositions comprising peptides consisting of fragments of fibroblast growth factor or vascular endothelial growth factor, claims 1-3, 15-21 28, 29, 32 and 33 are also drawn to compositions comprising immunogenic peptides of fibroblast growth factor or vascular endothelial growth factor.

8. Claims 4-23 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,919,459 (supra).

U.S. Patent 5, 919,459 discloses immunogenic compositions comprising fibroblast growth factor or vascular endothelial growth factor. Because the claims of the instant application are broadly drawn to compositions "comprising", the claimed compositions read on compositions having the entire fibroblast growth factor or vascular endothelial growth factor. Additionally, U.S. Patent 5,919,459 also teaches immunogenic compositions comprising fragments or immunogenic epitopes of fibroblast growth factor or vascular endothelial growth factor.

9. Claims 4-29 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent 5,919,459 (supra).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application of any unclaimed subject matter prior to the effective U.S. filing date of the reference under 37 CFR 1.131.

To the extent claims 4-29 read on compositions comprising combinations of fibroblast growth factor and vascular endothelial growth factor, the claims are obvious in view of the teachings of U.S. Patent 5,919,459 because U.S. Patent 5,919,459 teaches and claims either fibroblast growth factor or an immunogenic fragment thereof, or vascular endothelial growth factor or an immunogenic fragment thereof, and a second growth factor. Thus, U.S. Patent 5,9191,459 suggests making compositions comprising more than growth factor.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH
Anne L. Holleran
Patent Examiner
March 11, 2001